

FEB - 6 2001

LHASA MEDICAL, INC.

K003760

234 Libbey Parkway, Weymouth, MA 02189 (781) 340-1071 fax: 781-659-9916
(or fax: 781-335-6296)

January 22, 2001

Page 8a (revised from 12/5/00)

PRE-MARKET NOTIFICATION 510(k) SUMMARY
(As Required by 21 CFR 807.92)

(a)(1)

Submitter:

Lhasa Medical, Inc
234 Libbey Parkway
Weymouth, MA 02189
phone: (781) 340-1071

Contact Person:

Kyung P. Riihimaki

Date Summary Prepared:

January 22, 2001

(a)(2)

Name of Device:

Tai-Chi Acupuncture Needles

Common or Usual Name:

Acupuncture Needles

Classification:

Class II

510(k) Number:

K-003760

(a)(3)

The Tai-Chi Acupuncture Needle is substantially equivalent in design and performance to other brands of acupuncture needles which were in commercial distribution in the USA prior to May 28, 1976. The Tai-Chi Acupuncture Needle is also equivalent to acupuncture needles which have been found to be substantially equivalent through the 510(k) premarket notification process.

These include the following:

Hwa-To Acupuncture Needles

K-963299 (9/30/96)

Carbo Acupuncture Needles

K-961339 (7/3/96)

..... continued on next page

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PRE-MARKET NOTIFICATION 510(k) SUMMARY continued from previous page

(a)(4)

Description of the Tai-Chi Acupuncture Needle.

Tai-Chi Acupuncture Needles are sterile disposable, surgical s/steel Chinese acupuncture needles with Chinese spiral wound silver handles. Tai-Chi Acupuncture Needles are supplied individually blister sealed or bulk packaged with polypropylene insertion tubes.

(a)(5)

Tai-Chi Acupuncture Needles are used to pierce the skin in the practice of acupuncture (by qualified practitioners of acupuncture) as determined by the States.


(a)(6)

The Tai-Chi Acupuncture Needle has the same technological characteristics as the predicate devices identified in paragraph (a)(3). Tai-Chi Acupuncture Needles use the same needle body lengths and gauges (needle thickness); handle length and design (spiral wound); and packaging methods (single blister and bulk packaged) as these predicate devices. The Tai-Chi Needles also employ the same method of insertion with polypropylene guide tubes.

(b)(1)(2)(3)

Substantial equivalence is not based on an assessment of performance data.

(c) This summary includes these 2 pages in total.


Kyung P. Riihimaki, President

January 22, 2001

Date

Premarket Notification (510(k) Number): K-003760



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

FEB - 6 2001

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Kyung P. Riihimaki
President
Lhasa Medical, Incorporated
234 Libbey Parkway
Weymouth, Massachusetts 02189

Re: K003760
Trade Name: Tai-Chi Acupuncture Needles
Regulatory Class: II
Product Code: MQX
Dated: December 5, 2000
Received: December 6, 2000

Dear Mr. Riihimaki:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531

through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,



Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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510(k) Number (if known): K-003760

Device Name: Tai-Chi Acupuncture Needles

Indications For Use:

Tai-Chi Acupuncture Needles - Indications for Use

Tai-Chi Acupuncture Needles are used to pierce the skin in the practice of acupuncture as determined by the States".

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ☒
(Per 21 CFR 801.109)

OR

Over-The-Counter Use ☐

(Optional Format 1-2-96)

Adriana Ciccioli

(Device Sign-Off)

Device Infection Control,

Device Infection Control,

K003760